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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/599,870	06/23/2000	John D Brennan	086671/0109	1416

22428 7590 05/18/2004

FOLEY AND LARDNER  
SUITE 500  
3000 K STREET NW  
WASHINGTON, DC 20007

EXAMINER
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DO, PENSEE T

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/599,870

Applicant(s)

BRENNAN ET AL.

Examiner

Pensee T. Do

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 14-65 is/are pending in the application.
- 4a) Of the above claim(s) 14-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 50-65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The previous advisory action sent on April 13, 2004 is vacated in lieu of this final office action.

#### ***Amendment Entry & Claim Status***

The after-final response sent on January 22, 2003 was entered.

In the amendment to the claim, it is noted that applicant amended claim 55 which was previously a dependent claim from claim 54. However, claim 55 is now an independent claim. It is suspected that applicant meant to amend claim 50 instead of claim 55. Please verify.

Claims 50-65 are now pending.

#### ***Maintained Rejection(s)***

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 50-65 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure, which is not enabling. The reversibly disrupting factor, i.e. thermal, urea, GdHCl, is a critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

***The nature of the invention-*** the instant invention is directed to a carrier comprising a matrix of organic, inorganic, or organic and inorganic material and containing a biomolecular interaction entrapped within the matrix, wherein the biomolecular interaction comprises two or more biological species that can be reversibly dissociated from the other.

***The state of the prior art-*** the prior art fails to teach a carrier comprising a matrix of inorganic, or organic, or organic and inorganic material and a biomolecular interaction entrapped within the matrix wherein the biomolecular interaction comprises two or more species that can be reversibly dissociated from the other.

***The predictability or lack thereof in the art-*** in view of the lack of teachings in the prior art that shows or suggests a biomolecular interaction, entrapped within the matrix, wherein the biomolecular interaction comprises two or more species that can be reversibly dissociated from the other, the level of predictability is low. While it may be possible to reversibly dissociate the

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biological species of the biomolecular interaction by adding GdHCl or urea or subjecting the biomolecular interaction under thermal condition as described in the instant specification, it has not been shown that the biomolecular interaction can be reversibly dissociated by itself or by adding other compounds.

***The amount of direction or guidance present*** – the instant specification provides guidance for reversibly dissociating the biomolecular interaction using only urea, GdHCl, or subjecting such biomolecular interaction to thermal condition- see example 3, page 32.

***The absence of working examples*** – the examples disclosed in the specification only show reversibly dissociating the biomolecular interaction by adding urea, GdHCl or thermal condition.

***The quantity of experimentation necessary*** – it would require an undue amount of experimentation for a skilled artisan to make and use the invention as claimed.

***The relative skill of those in the art***- the level of skill in the art is high.

***The breadth of the claims*** – the claimed carrier comprises a matrix of organic, inorganic, or organic and inorganic material and a biomolecular entrapped within the matrix wherein the biomolecular interaction comprises two or more biological species that can be reversibly dissociated from each other.

The instant specification describes that the biological species of the biomolecular interaction can be reversibly dissociated from each other only when a reversibly disrupting factor such as urea, GdHCl, or thermal is applied. Without such reversibly disrupting factor, the complex or biomolecular interaction would

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not be disrupted and thus reversibly dissociation would not take place. The instant specification fails to teach any other possible factor which would reversibly dissociate the biomolecular interaction or that the biomolecular interaction would reversibly dissociate on its own-without the aid of a disrupting factor. At best, the instant specification is enabled for a carrier comprising a matrix of organic, inorganic, organic and inorganic material, a biomolecular interaction entrapped within the matrix, wherein the biomolecular interaction can be reversibly dissociated from each other when adding urea, GdHCl, or thermal/heat, but the specification is not enabled for a biomolecular interaction that can reversibly dissociate on its own or by any other compounds. An undue amount of experimentation would be required to identify any possible reversibly dissociating compounds for reversibly dissociating the biomolecular interaction entrapped within the matrix of the carrier.

### ***Response to Arguments***

Applicant's arguments filed on January 22, 2003 have been fully considered but they are not persuasive.

Applicant argues that the claims do not need to be limited to specific dissociating factors since the invention is not directed to novel biomolecular interactions. The claims are currently directed to a carrier that comprises a biomolecular interaction entrapped within a matrix, wherein the biomolecular interaction comprises at least two biological species that can be reversibly dissociated from the other within the matrix. The ability to reversibly dissociate within the matrix is important and is a characteristic that defines the carrier

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claimed. Applicant also argues that a person skilled in the art would appreciate that denaturations or other molecules, such as antagonists of the biomolecular interaction, can cause the reversible dissociation in the invention.

Applicant submits that the invention is directed to a carrier that comprises a biomolecular interaction entrapped within a matrix, wherein the biomolecular interaction comprises at least two biological species that can be reversibly dissociated from the other within the matrix. For two species of a biomolecular interaction to be reversibly dissociated from each other, an external factor must be present for catalyzing such reverse dissociation. Such external factor can be heat, or pH as applicants has mentioned. However, for the dissociation to happen within the matrix, such factor must be present within the matrix of the carrier. These biological species cannot dissociate by themselves within the matrix of the carrier. One of ordinary skills in the art would find that the biological species could reversibly dissociate using a denaturation molecule or an antagonist in other environment other than within the matrix of a carrier. One of ordinary skills in the art would not be able to know that the biological species reversibly dissociate within the matrix of a carrier using the same conventional denaturation molecules or antagonists. Thus, the conditions or factors that promote the dissociation of the biological species within the matrix of a carrier must be specified.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 571-272-0819. The examiner can normally be reached on Monday-Friday, 7:00-3:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pensee T. Do  
Patent Examiner  
May 13, 2004

  
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05/13/04